Technology Assessment Program

Office of Patient Care Services

UPDATED INFORMATION FOR VA TECHNOLOGY ASSESSMENT PROGRAM (VATAP) REPORTS

In June 2000, VATAP was relocated within the Veterans Health Administration from the Office of Research & Development to the Office of Patient Care Services. The following report was produced prior to the relocation of VATAP.

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Appendix 9

Experience With PET in VHA

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Appendix 9

Experience With PET in VHA

Veterans Health Administration (VHA), shares the ownership and operation of 10 positron emission tomography (PET) imaging facilities with some of its academic affiliates. Significant resource commitments are associated with the acquisition, maintenance, and operation of these facilities.

In late 1993, the Acting Under Secretary for Health in VHA requested that the Management Decision and Research Center (within Health Services Research and Development Service) conduct a rigorous examination of the agency's investment in PET. The Acting Under Secretary asked two questions:

- *Should the VHA add more PET Centers?*
- *How is PET used in VHA today?*

The Advisory Committee to the PET assessment focused the assessment on the use of PET in diagnosing diseases relevant to the veteran population and on collecting information about PET imaging utilization, center operations, and clinical and research activities.

To obtain information on the experience with PET within VHA, a written survey was distributed prior to the site visits, and a follow-up survey was sent out in December, 1995. Site visits were conducted by a MDRC Technology Assessment Management and Program Analyst and an external consultant from August through October, 1994.

This text briefly summarizes the information obtained by the MDRC Technology Assessment Program on the experience at 11 VHA PET centers.

I. BACKGROUND

PET is a relatively new addition to the repertoire of clinical diagnostic tests available both within and outside VHA. All but three of the VHA PET facilities became operational after 1990, and the information collected through the site visits and surveys represents preliminary data on VHA experience with the technology.

Of the 12 initially approved PET sites, 11 were fully operational at the time of the assessment; support for the twelfth had been withdrawn. After completion of the site visits, support for another PET center was discontinued by local VA medical center administration. At the time of release of this report, 10 VHA PET centers were in operation. Locations of the VHA PET centers are depicted in Figure 1 at the end of this section.

II. METHODS

A written survey addressing characteristics and staffing of PET installations, characteristics of the medical centers where the PET facilities were housed, and the types and volume of PET studies was distributed to each PET center approximately three to four weeks prior to the site visits.

Preparation for the site visits was made with the assistance of the PET director and/or the Chief, Nuclear Medicine Service at each VHA site, who acted as the primary contact person. The contact person was responsible for compiling a list of interview subjects and coordinating the interview schedule. For this interview schedule he or she was asked to include referring and non-referring physicians from all sharing partners and within four major specialties: cardiology, neurology, oncology, and psychiatry. These specialties represent the clinical areas where PET is most likely to be used. The contact persons were encouraged to include other specialties deemed important to the activities of their PET centers.

At nine sites, interviews were conducted over two days. The two remaining sites required only one day to cover their referral bases. Most interviews were completed in 30 minutes, and confidentiality of interview content was stressed.

The written survey and interview questionnaires may be found at the end of this appendix.

III. RESULTS

The information in this section was obtained from pre-site visit survey materials, from responses of interview subjects based on the interview questionnaires, and from observations made by the site visit team. Results of the pre-site visit survey are summarized in Tables 1 through 11 and are described in the sections “Characteristics of interview subjects,” “Characteristics of PET centers” and “Types and volumes of PET studies.” The section on “Costs” is also based on pre-site visit survey data. Results from the 1995 follow up survey are presented in Table 12.

Results of the site visit interviews are summarized in Tables 13 through 16 and are described in the sections “Barriers and incentives to PET use,” “Sharing agreements,” and “Research activity at VHA PET Centers.” Issues related to the negotiation and content of the sharing agreements and to the research activity of these PET centers were felt to be of sufficient importance to be discussed in separate sections. A summary is provided at the end of this section.

A. Characteristics of interview subjects

The composition of interview subjects is presented in the following pages in Table 1 and is summarized in Tables 2 through 4. There was an equitable distribution of clinical specialties represented among interview subjects. The majority of subjects interviewed were classified as referrers, of which 7% referred fewer than 5 patients annually and another 34% referred an unknown number of patients annually for PET scans. The vast majority of interview subjects had multiple job roles consisting primarily of clinical and research duties with some administrative component, reflecting the academic environments in which these PET centers were placed.

B. Characteristics of PET centers

Table 5 compares the ancillary services available at VHA PET centers. To the extent that these services might be associated with the use of PET (e.g., a wide range of cardiology or neurology diagnostic services are available), most of the VHA centers seem to have an appropriate and relatively equivalent array of services.

Table 6 provides general information on the characteristics of VHA PET facilities. Table 7 summarizes the data in Table 6. Most of the PET centers became operational within the last three years. The data reflect a range of scanner models used across sites. Ownership and location of the scanner were evenly distributed among VAMCs and their sharing partners, whereas ownership and location of the cyclotron tended to be concentrated among the sharing partners (i.e., academic affiliates). Thus, the sharing partner was inclined to be the primary source of the radiotracers used in PET scanning.

All sites used cyclotron produced radioisotopes as tracers. Fluorodeoxyglucose (FDG) was the only radiopharmaceutical common to all sites. Many sites generated and used ^{15}O-water and ^{13}N-ammonia, as well. Responsibility for personnel was evenly divided among VAMCs and their sharing partners.

Table 1: Site Visit Interview Subjects According to Specialty, Job Role, and Referral Status

Note: Data reporting annual referral patterns of clinicians and researchers excluded interview subjects classified as administrators only and non-referring specialties.

Site	Specialty	Interview Subjects With a Single Role			Interview Subjects With Multiple Roles				Total (% Site Total)	Annual Referral Patterns of Clinicians and Researchers Listed in Columns to Left			
		Administrator	Clinician	Researcher	Administrator/ Clinician	Administrator/ Researcher	Clinician/ Researcher	Admin/ Clinician/ Researcher		Non-referrer	Referrer (number of patients referred annually)		
											(1-5)	(>5)	Unknown
A	nonclinical	1							1 (5)				
	cardiology						3	1	4 (21)				4
	neurology						3	2	5 (26)			1	3
	oncology					1	1		2 (10)	1			1
	psychiatry			1		1	2		4 (21)	1		1	2
	other	1						2	3 (16)				2
							Total for Site		**19 (100)**				
B	non-clinical	1							1 (6)				
	cardiology						1	3	4 (25)			4	
	neurology				1		2		3 (19)		2	1	
	oncology						2	2	4 (25)	1		3	
	psychiatry							2	2 (13)	2			
	other	1						1	2 (13)				
							Total for Site		**16 (100)**				
C	non-clinical	3				1			4 (31)	1			
	cardiology							2	2 (15)		1	1	
	neurology							2	2 (15)			2	
	oncology							1	1 (8)	1			
	psychiatry							1	1 (8)	1			
	other							3	3 (23)	1		1	
							Total for Site		**13 (100)**				

Site	Specialty	Interview Subjects With a Single Role			Interview Subjects With Multiple Roles				Total (% Site Total)	Annual Referral Patterns of Clinicians and Researchers Listed in Columns to Left			
		Administrator	Clinician	Researcher	Administrator/ Clinician	Administrator/ Researcher	Clinician/ Researcher	Administrator/ Clinician/ Researcher		Non-referrer	Referrer (number of patients referred annually)		
											(1-5)	(>5)	Unknown
D	non-clinical	3							3 (17)				
	cardiology						1	1	2 (11)			2	
	neurology						3	1	4 (22)	1	1	2	
	oncology							3	3 (17)	1		2	
	psychiatry							2	2 (11)	2			
	other						1	3	4 (22)	1		2	
							Total for Site		**18 (100)**				
E	non-clinical			1					1 (6)	1			
	cardiology						3	1	4 (22)			4	
	neurology				1		1	2	4 (22)	1	2		
	oncology		1					2	3 (17)	1		2	
	psychiatry							3	3 (17)	2			1
	other		1				1	1	3 (17)	1	1		
							Total for Site		**18 (100)**				
F	non-clinical	1							1 (7)				
	cardiology						2	1	3 (21)		2		
	neurology						4		4 (29)			2	2
	oncology		1				1	1	3 (21)			3	
	psychiatry							1	1 (7)	1			
	other		1					1	2 (14)				
							Total for Site		**14 (100)**				

Site	Specialty	Interview Subjects With a Single Role			Interview Subjects With Multiple Roles				Total (% Site Total)	Annual Referral Patterns of Clinicians and Researchers Listed in Columns to Left			
		Administrator	Clinician	Researcher	Administrator/ Clinician	Administrator/ Researcher	Clinician/ Researcher	Administrator/ Clinician/ Researcher		Non-referrer	Referrer (number of patients referred annually)		
											(1-5)	(>5)	Unknown
G	non-clinical	1							1 (8)				
	cardiology						1	1	2 (15)	2			
	neurology						2	1	3 (23)	1		1	1
	oncology						1		1 (8)	1			
	psychiatry						1		1 (8)				1
	other						2	3	5 (38)	2			
							Total for Site		**13 (100)**				
H	non-clinical	5							5 (15)				
	cardiology					4			4 (12)				4
	neurology						6		6 (18)				6
	oncology						4	1	5 (15)				5
	psychiatry						6	1	7 (21)				6
	other	1					3	2	6 (18)				4
							Total for Site		**33 (100)**				
I	non-clinical								0 (0)				
	cardiology						2	1	3 (16)			1	2
	neurology						2	4	6 (32)	2		3	1
	oncology		1				1		2 (11)	1			1
	psychiatry						2	1	3 (16)		1	2	
	other				1		2	2	5 (26)			1	1
							Total for Site		**19 (100)**				

Site	Specialty	Interview Subjects With a Single Role			Interview Subjects With Multiple Roles				Total (% Site Total)	Annual Referral Patterns of Clinicians and Researchers Listed in Columns to Left			
		Administrator	Clinician	Researcher	Administrator/ Clinician	Administrator/ Researcher	Clinician/ Researcher	Administrator/ Clinician/ Researcher		Non-referrer	Referrer (number of patients referred annually)		
											(1-5)	(>5)	Unknown
J	non-clinical								0 (0)				
	cardiology						2	1	3 (23)			3	
	neurology						2	2	4 (31)	1		1	2
	oncology						2	1	3 (23)			1	1
	psychiatry						1		1 (8)			1	
	other	1						1	2 (15)				
							Total for Site		**13 (100)**				
K	non-clinical	1							1 (6)				
	cardiology							2	2 (13)			2	
	neurology						1	1	2 (13)			2	
	oncology						1	2	3 (19)			2	1
	psychiatry						1	1	2 (13)	2			
	other						1	5	6 (38)	1		1	
							Total for Site		**16 (100)**				

Table 2: Summary of Site Visit Interview Subjects According to Specialty

Specialty	*Total (% Total Subjects Interviewed)*
non-clinical	18 (9)
cardiology	33 (17)
neurology	43 (22)
oncology	30 (16)
psychiatry	27 (14)
other	41 (21)
TOTAL	192 (100)

Table 3: Summary of Site Visit Interview Subjects According to Referral Patterns

Annual Referral Patterns	*Total (% Total Subjects Interviewed)**
non-referrer	34 (23)
1-5 patients	10 (7)
>5 patients	54 (36)
referred unknown number	51 (34)
TOTAL	149 (100)

*Note: Total number excludes interview subjects classified as non-clinical and non-referring specialties

Table 4: Summary of Site Visit Interview Subjects According to Job Role

Job Role (s)	*Administrator*	*Clinician*	*Researcher*	*Administrator/ Clinician*	*Administrator/ Researcher*	*Clinician/ Researcher*	*Administrator/ Clinician/ Researcher*	*TOTAL*
Total (% Total Subjects Interviewed)	20 (10)	5 (3)	2 (1)	3 (2)	7 (4)	77 (40)	78 (41)	192 (100)

Table 5: A Comparison Of Ancillary Services Offered At Each VHA PET Site

Service	*Sites Offering Service (%)*
Alcohol Dependency Treatment Unit	100
Cancer Center	82
Cardiac Cath Lab	100
Cardiac ICU	100
Cardiac Surgery Program	100
Electron Microscopy	73**
Epilepsy Program	100
Geriatric Research Education & Clinical Center (GRECC)	91**
Health Psychology Program	45**
Hemodialysis In-Center Care	91
Home Dialysis and CAPD Training	100
Hypertension Screening and Treatment Program	100
Medical ICU	100
Mental Hygiene Clinic	100
Neuropsychological Testing	100
Nursing Home Care Unit	91
Patient Health Education Program	91
Prosthetic and Sensory Aid Service	100
PTSD Program	91
Pulmonary Function Lab	100
Sickle Cell Screening Program	53
Speech Pathology Lab	91**
Surgical ICU	100
Women's Health Center	64**
Other: (Nuclear Medicine Network)	9

** reflects uncertainty of some respondents in whether a service was offered; actual percentage may be higher

Table 6: General Information of VHA PET Sites as of Fiscal Year 1994

Site	Start-up Year	Scanner Model	Owner of Scanner	Owner of Cyclotron	Owner of Radiochem Lab	Location of Camera	Location of Cyclotron and Lab	Personnel Employer	FDG Source	Radiopharmaceuticals Generated or Used
A	1993	Positron Posicam	VA and SP	VA and SP	VA and SP	VA	VA	VA and SP	VA	^{18}F-FDG, ^{13}N-Ammonia, ^{18}F-DOPA
B	1992	Siemens 951/31	VA and SP	SP	SP	SP	SP	SP	SP	^{18}F-FDG, ^{13}N-Ammonia
C	1992	Siemens 951R	VA and SP	SP	SP	SP	SP	SP	SP	^{18}F-FDG, ^{13}N-Ammonia, ^{15}O-Water
D	1988	Siemens 931/08-12	VA and SP	SP	SP	SP	SP	SP	SP	^{18}F-FDG, ^{13}N-Ammonia, ^{15}O-Water, ^{11}C-Acetate
E	1993	Siemens 951R	VA and SP	VA and SP	VA and SP	SP	SP	SP	SP	^{18}F-FDG, ^{13}N-Ammonia, ^{15}O-Water, ^{11}C-Acetate
F	1979	Siemens 933 & GE Advance	VA and SP	SP	SP	VA	SP	VA and SP	SP	^{18}F-FDG, ^{13}N-Ammonia, ^{15}O-Water, ^{18}F-DOPA, ^{18}F-Methane, ^{18}F-Lomafloxacin, ^{62}Cu-PTSM, ^{60}Cu-PTSM, ^{94m}Tc-Teboroxyine, ^{94m}Tc-Sestamibi
G	1992	Siemens 953B	VA	VA	VA	VA	VA	VA	VA	^{18}F-FDG, ^{15}O-Water
H	1992	GE 4096	VA and SP	VA and SP	VA and SP	SP	SP	VA and SP	SP	^{18}F-FDG, ^{13}N-Ammonia, ^{15}O-Water
I	1985	Siemens 953/31	VA	VA	VA	VA	VA	VA	VA	^{18}F-FDG, ^{13}N-Ammonia, ^{15}O-Water
J	1991	Siemens 931/04	VA	None	None	VA	Private Source	VA	Private Source	^{18}F-FDG, ^{18}F
K	1993	Siemens 951/31	VA and SP	VA and SP	SP	VA	SP	VA and SP	SP	^{18}F-FDG, ^{13}N-Ammonia, ^{15}O-water

SP=Sharing Partner
^{11}C= carbon-11
^{60}Cu=copper-60
^{62}Cu= copper-62
DOPA= dihydroxyphenylalanine
^{18}F= fluorine-18
FDG= fluorodeoxyglucose
^{13}N= nitrogen-13
^{15}O= oxygen-15
PTSM= pyruvaldehyde bis(N4-methylthiosemicorbazone)
^{94m}Tc=Technetium-94m

Table 7: Summary of the General Characteristics of the VHA PET Sites

Characteristic		*Frequency* Number (%)
Description	***Options***	
Start up year	1979	1 (9)
	1985	1 (9)
	1988	1 (9)
	1991	1 (9)
	1992	4 (36)
	1993	3 (27)
Scanner model (some sites have > 1 scanner)	Positron Posicam	1 (8)
	Siemens 951/31	3 (25)
	Siemens 951/R	2 (17)
	Siemens 931/08-12	1 (8)
	Siemens 933	1 (8)
	GE advance	1 (8)
	Siemens 953B	1 (8)
	GE 4096	1 (8)
	Siemens 931/04	1 (8)
Owner of scanner	VA	3 (27)
	VA and sharing partner	8 (73)
Owner of cyclotron	VA	2 (20)
	Sharing partner	4 (40)
	VA and sharing partner	4 (40)
Owner of radiochemistry lab	VA	2 (20)
	Sharing partner	5 (50)
	VA and sharing partner	3 (30)
Location of camera	VA	6 (55)
	Sharing partner	5 (45)
Location of cyclotron	VA	3 (27)
	Sharing partner	7 (64)
	Private source used	1 (9)
Personnel employer	VA	3 (27)
	Sharing partner	4 (36)
	VA and sharing partner	4 (36)
FDG source	VA	3 (27)
	Sharing partner	7 (64)
	Private vendor	1 (9)
Radiopharmaceuticals	FDG	11 (100)
	^{13}N-ammonia	9 (82)
	F-DOPA	2 (18)
	^{15}O-water	8 (73)
	other	4 (36)

C. Types and volumes of PET studies

Tables 8 and 9 present information on the types and volumes of clinical and research studies conducted at each VHA PET center and its academic affiliate for Fiscal Year 1994; Tables 10 and 11 provide the same information for Fiscal Year 1993. Table 12 presents data from a follow-up survey on total patient volume for Fiscal Year 1995 and related issues.

Inter-site comparisons using these data were problematic for a number of reasons. There was significant variability among protocols with respect to scan time and resources used; some patients were scanned multiple times. Most sites logged their utilization according to patient and protocol, rather than the actual time involved in acquiring PET studies. Variations in PET technology across sites also affected utilization, as the scanning process took longer with older models.

Volume comparisons across sites using total number of scans would require a standardized workload unit and prospective data collection. The MDRC Technology Assessment (TA) Program felt that expressing patient volume according to the number of patients studied best reflected the referral base of each site. Therefore, comparisons using total number of patients rather than total number of scans were made.

The MDRC TA Program was asked to evaluate the level of patient activity at each site. Therefore, animal studies were not included in the volume data. Four of the eleven sites performed PET scans on animals, for a total of 279 studies in 1994 and 256 in 1993.

The tables indicate that a wide range of types and volumes of studies are performed across the VHA system. In 1993, there was a small overall disparity in utilization between VHA and its academic affiliates (45% and 55% of the total studies performed, respectively). The majority of PET studies was conducted for clinical purposes in neurology applications, followed by cardiology and oncology. The vast majority of research activity was in neurology and psychiatry.

In 1994, the disparity in utilization between VHA and its academic affiliates had widened to 31% and 69%, respectively. Clinical neurology applications continue to be the main focus of activity at these PET centers, followed by oncology and cardiology. The vast majority of research activity was in neurology and psychiatry with a growing interest in oncology.

Data on total volume for Fiscal Year 1995 were obtained from all but one site, which is no longer supported by VHA, but continues to be supported by the university affiliate. In 1995 the disparity in utilization between VA and non-VA studies was decreased to 41% and 59%, respectively. Seven sites reported an increased demand for clinical PET studies, while one reported a decrease and two reported no change. The increase in clinical interest was attributed largely to clinical oncology applications. Two sites expressed an increased use of PET in psychiatric and neurologic research.

Table 8: Patient Volume at VHA PET Sites for Fiscal Year 1994

Note: Definition of clinical oncology studies varied across sites. Clinical psychiatry studies listed were for the diagnosis of manic depression or schizophrenia. Those data not reported or available were indicated as "N/A".

Site	Patient Type	Cardiology Studies					Neurology Studies					Psychiatry Studies		Oncology Studies		Other	Clinical Total (% Site Total)	Research Total (% Site Total)	Site Total (% of system-wide total)
		Clinical				Research	Clinical				Research	Clinical	Research	Clinical	Research	Research			
		Viability	Ischemic Heart Disease	Other	Subtotal		Epilepsy	Tumor vs. necrosis	Other	Subtotal									
C	VA	N/A	N/A	0	0	0	3	0	0	3	0	0	0	0	0	0	3 (1)	0 (0)	339 (17)
	non-VA	N/A	N/A	0	0	0	3	15	0	18	267	0	0	0	51	0	18 (5)	318 (94)	
E	VA	26	1	0	27	0	6	0	0	6	0	0	0	21	0	0	54 (17)	0 (0)	327 (16)
	non-VA	48	18	0	66	0	74	2	5	81	1	1	0	122	2	0	270 (83)	3 (1)	
I	VA	7	0	0	7	10	51	0	1	52	10	0	0	54	0	0	113 (41)	20 (7)	278 (14)
	non-VA	0	0	0	0	0	16	0	0	16	0	0	0	129	0	0	145 (52)	0 (0)	
G	VA	6	0	0	6	0	0	0	0	0	21	0	15	0	0	0	6 (3)	36 (17)	208 (11)
	non-VA	0	0	0	0	0	4	1	0	5	113	0	48	0	0	0	5 (2)	161 (77)	
A	VA	N/A	N/A	0	0	0	0	0	48	48	25	0	0	0	0	0	48 (25)	25 (13)	193 (10)
	non-VA	N/A	N/A	0	0	0	N/A	N/A	77	77	43	0	0	0	0	0	77 (40)	43 (22)	
F	VA	0	0	0	0	0	15	0	5	20	0	0	0	0	1	0	20 (12)	1 (0.1)	171 (9)
	non-VA	5	22	0	27	14	13	23	0	36	22	0	41	0	10	0	63 (37)	87 (51)	
D	VA	14	0	N/A	14	0	45	0	0	45	52	0	14	0	0	25	59 (39)	91 (61)	150 (8)
	non-VA	N/A	N/A	N/A	0	N/A	N/A	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A	0	0 (0)	0 (0)	
B	VA	2	2	0	4	0	15	12	3	30	0	3	0	20	0	0	57 (54)	0 (0)	105 (5)
	non-VA	8	7	0	15	0	5	6	1	12	0	1	0	20	0	0	48 (46)	0 (0)	
K	VA	23	3	0	26	0	0	3	0	3	9	0	0	0	14	0	29 (34)	23 (26)	87 (4)
	non-VA	8	0	0	8	0	5	0	0	5	16	0	0	0	6	0	13 (15)	22 (25)	
H	VA	2	0	0	2	0	0	0	0	0	0	0	17	0	0	0	2 (2)	17 (20)	84 (4)
	non-VA	5	1	0	6	2	9	0	0	9	33	0	15	0	0	0	15 (18)	50 (59)	
J	VA	13	0	0	13	0	0	1	1	2	0	0	0	7	0	0	22 (44)	0 (0)	50 (2)
	non-VA	4	0	0	4	0	17	4	0	21	0	0	0	3	0	0	28 (56)	0 (0)	
TOTAL		171	54	0	225	26	281	67	141	489	612	5	150	376	84	25	1095	897	1992 (100

Table 9: A Comparison of VA to Non-VA Patient Volume Within Each Clinical and Research Application Across All VHA PET Sites for Fiscal Year 1994

Note: Definition of clinical oncology studies varied across all sites. Clinical psychiatry studies listed were for the diagnosis of manic depression or schizophrenia. Those data not reported or available were indicated as "N/A".

PATIENT TYPE	CARDIOLOGY VOLUME (% COLUMN TOTAL)				NEUROLOGY VOLUME (% COLUMN TOTAL)				PSYCHIATRY VOLUME (% COLUMN TOTAL)		ONCOLOGY VOLUME (% COLUMN TOTAL)		OTHER VOLUME (% COLUMN TOTAL)	TOTAL (% COLUMN TOTAL)
	Clinical Studies				Clinical Studies									
	Viability	Ischemic Heart Disease	Other	Research	Epilepsy	Tumor vs. Necrosis	Other	Research	Clinical	Research	Clinical	Research	Research	
VA	93 (54)	6 (11)	0	10 (38)	135 (48)	16 (24)	58 (41)	108 (18)	3 (60)	46 (31)	108 (29)	15 (18)	25 (100)	623 (31)
non-VA	78 (46)	48 (89)	0	16 (62)	146 (52)	51 (76)	83 (59)	504 (82)	2 (40)	104 (69)	268 (71)	69 (82)	0 (0)	1369 (69)
Total VA + non-VA	171 (100)	54 (100)	0 (100)	26 (100)	281 (100)	67 (100)	141 (100)	612 (100)	5 (100)	164 (100)	376 (100)	84 (100)	25 (100)	1992 (100)
Total (% PET activity systemwide)	171 (9)	54 (3)	0 (0)	26 (1)	281 (14)	67 (3)	141 (7)	612 (31)	5 (0.2)	150 (8)	376 (19)	84 (4)	25 (1)	1992 (100)

Table 10: Patient Volume at VHA PET Sites for Fiscal Year 1993

Note: Definition of clinical oncology studies varied across sites. Clinical psychiatry studies listed were for the diagnosis of manic depression or schizophrenia. Those data not reported or available were indicated as "N/A".

Site	Patient Type	Cardiology Studies					Neurology Studies					Psychiatry Studies		Oncology Studies		Other	Clinical Total (% Site Total)	Research Total (% Site Total)	Site Total (% of system-wide total)
		Clinical				Research	Clinical				Research	Clinical	Research	Clinical	Research	Research			
		Viability	Ischemic heart disease	Other	Subtotal		Epilepsy	Tumor vs. necrosis	Other	Subtotal									
I	VA	4	0	0	4	13	115	0	21	136	71	0	1	162	0	0	302 (69)	85 (19)	439 (25)
	non-VA	0	0	0	0	0	16	11	0	27	1	0	0	24	0	0	51 (12)	1 (0.2)	
A	VA	58	58	0	116	0	0	0	48	48	31	0	0	0	0	0	164 (59)	31 (11)	278 (16)
	non-VA	4	4	0	8	0	20	5	0	25	50	0	0	0	0	0	33 (12)	50 (18)	
D	VA	18	18	3	39	0	0	0	51	51	31	0	31	0	0	26	90 (51)	88 (49)	178 (10)
	non-VA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A			
E	VA	13	1	0	14	0	0	6	0	6	0	0	0	8	0	0	28 (19)	0 (0)	149 (9)
	non-VA	35	1	0	36	0	33	6	0	39	0	0	0	46	0	0	121 (81)	0 (0)	
F	VA	7	0	0	7	0	8	2	0	10	0	0	0	0	0	0	17 (12)	0 (0)	140 (8)
	non-VA	8	10	0	18	3	35	5	0	40	27	0	33	0	0	2	58 (42)	65 (46)	
C	VA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0 (0)	0 (0)	137 (8)
	non-VA	0	0	0	0	0	0	0	0	0	3	0	134	0	0	0	0 (0)	137 (100)	
G	VA	0	0	0	0	0	0	1	1	2	28	0	0	0	0	0	2 (2)	28 (28)	99 (6)
	non-VA	0	0	0	0	0	12	4	0	16	45	0	8	0	0	0	16 (16)	53 (54)	
J	VA	10	0	0	10	0	0	2	10	12	0	0	0	6	0	1	28 (31)	1 (1)	91 (5)
	non-VA	22	0	0	22	0	21	4	1	26	0	0	13	1	0	0	49 (54)	13 (14)	
H	VA	0	0	0	0	0	0	0	0	0	0	0	27	0	0	0	0 (0)	27 (34)	80 (5)
	non-VA	0	0	0	0	0	2	0	0	2	18	0	25	0	0	8	2 (2)	51 (64)	
B	VA	4	4	0	8	0	4	7	2	13	0	0	0	5	0	0	26 (39)	0 (0)	66 (4)
	non-VA	10	10	0	20	0	6	2	1	9	0	0	0	11	0	0	40 (61)	0 (0)	
K	VA	33	0	0	33	0	0	0	0	0	1	0	0	0	3	0	33 (52)	4 (6)	63 (4)
	non-VA	3	0	0	3	0	12	11	0	23	0	0	0	0	0	0	26 (41)	0 (0)	
TOTAL		229	106	3	338	16	284	66	135	485	306	0	272	263	3	37	1086	634	1720 (100)

Table 11: A Comparison of VA to Non-VA Patient Volume Within Each Clinical and Research Application Across All VHA PET Sites for Fiscal Year 1993

Note: Definition of clinical oncology studies varied across sites. Clinical psychiatry studies listed were for the diagnosis of manic depression or schizophrenia.

PATIENT TYPE	CARDIOLOGY VOLUME (% OF ALL CARDIOLOGY STUDIES)				NEUROLOGY VOLUME (% OF ALL NEUROLOGY STUDIES)				PSYCHIATRY VOLUME (% OF ALL PSYCHIATRY STUDIES)		ONCOLOGY VOLUME (% OF ALL ONCOLOGY STUDIES)		OTHER VOLUME (% OF ALL OTHER STUDIES)	TOTAL (% TOTAL STUDIES)
	Clinical Studies			Research	Clinical Studies			Research	Clinical	Research	Clinical	Research	Research	
	Viability	Ischemic Heart Disease	Other		Epilepsy	Tumor vs. Necrosis	Other							
VA	147 (64)	81 (76)	3 (100)	13 (81)	127 (45)	18 (27)	133 (99)	162 (53)	0	59 (22)	181 (69)	3 (100)	27 (73)	954 (55)
non-VA	82 (36)	25 (24)	0	3 (19)	157 (55)	48 (73)	2 (1)	144 (47)	0	213 (78)	82 (31)	0	10 (27)	766 (45)
Total VA + non-VA	229 (100)	106 (100)	3 (100)	16 (100)	284(100)	66 (100)	135 (100)	306 (100)	0	272 (100)	263 (100)	3 (100)	37 (100)	1720 (100)
Total (% PET activity systemwide)	229 (13)	106 (6)	3 (0.1)	16 (1)	284 (17)	66 (4)	135 (8)	306 (18)	0	272 (16)	263 (15)	3 (0.2)	37 (2)	1720 (100)

Table 12: Follow-up Survey of Activity at VHA PET Sites for Fiscal Year 1995

Note: Data are presented in order of total patients scanned.

A list of abbreviations is located at the end of the table.

Site	Number of Patients Studied		Number of Animals Studied	Change in demand for clinical studies from FY '94 to FY '95 and comments	Impact of proposed changes in FDA regulations on center	Comments on proposed changes in FDA regulations	Comments on trends experienced in last year
	VA	non-VA					
B	204	416	0	**increased** due to: • interest in oncology • growing interest among referring physicians	will modify PET center operations in FY '96	anticipate the need to submit NDA or ANDA in FY '96	• low interest in cardiac applications • 90-95% of studies in clinical oncology to determine extent of disease and response to therapy where traditional anatomic studies (CT,MRI) are equivocal • approaching daily capacity of system at 3-4 cases/day
I	301	230	0	**increased** due to: • interest in oncology	will modify PET center operations in FY '96	refurbishing lab area to include an automated FDG system	increasing interest and utilization of ^{15}O-water studies with applications in various central nervous system activation paradigms and vascular studies of extremities
A	241	210	3	**increased** due to: • enhanced contact with referral staff • educating medical community • reimbursement negotiated with local carrier • approval by local authority for oncology procedures	will modify PET center operations in FY '96	will work to meet requirements for good manufacturing practices to meet FDA regulations	• increased acceptance of PET by medical community • plan to increase marketing efforts • will further develop support for oncology referrals and reimbursements
G		357	2	**no change**	modified PET center operations in FY '95	District Counsel has written an opinion stating that FDA has no authority over PET scanning at VAMC	
C	3	312	44	**decreased** due to: • lack of reimbursement (for mostly non-VA patients) • fewer cardiology but more oncology studies	• modified PET center operations in FY '95 and FY '96 • plan to coordinate activities with other PET centers	• changes would be problematic should site wish to manufacture pharmaceuticals for distribution • state-of-the-art facility; some requirements already in place • confusion regarding new GMPs and their application to PET, given that all products are already tested before administration to patient	
E	77	183	72	**no known changes**	will modify PET center operations in FY '96	plan to obtain Investigative New Drug application	
K	199*	35*	11*	**increased** due to: • interest in oncology	none	none reported	none reported

Site	Number of Patients Studied		Number of Animals Studied	Change in demand for clinical studies from FY '94 to FY '95 and comments	Impact of proposed changes in FDA regulations on center	Comments on proposed changes in FDA regulations	Comments on trends experienced in last year
	VA	non-VA					
J	99	41	0	**increased** due to: • installation of whole body scanner • interest in oncology	none	none reported	• PET has replaced CT as next test following x-ray in evaluation of solitary pulmonary nodules • PET is used clinically in patients with lung cancer, colorectal cancer, lymphoma, and melanoma
H	25	99	0	**increased** due to: • expanding referral base (for evaluation of patients with seizure disorders and tumor patients for pre-operative brain mapping • reimbursement from private carriers and limited considerations from Medicare and Medicaid for seizure studies	will modify PET center operations in FY '96	establishing a contractual agreement with an outside company to use the VHA PET facility for distribution of FDG; agreement will include using the FDG provided by them under their NDA for all clinical studies	• plan to increase clinical emphasis as a source of revenue and to continue this trend in FY 1996 by implementing PET oncology studies • PET center staffing is decreasing; currently one PET technologist at the center; one sharing partner discontinued support for personnel.
D	104	0	0	**increased** due to: • interest among referring physicians to use PET for differential diagnosis and designing treatment plans	will modify PET center operations in FY '96	GMP regulations may jeopardize present sharing agreements	• majority of referrals are for tumor localization in clinical oncology • PET used for research in alcohol, alcohol treatment, and PTSD • PET used to study medical/social problems; findings announced in media
F**	---	---	---	---	---	---	---
Total (% Total)	1251 (40%)	1863 (60%)	---	---	---	---	---

*excluding a total of 77 research studies
**VHA discontinued its support in 1995; now supported by university affiliate

Abbreviations: GMP=good manufacturing practices
CT=computerized tomography
MRI= magnetic resonance imaging
PTSD=post traumatic stress disorder
NDA=new drug application
ANDA=abbreviated new drug application

D. Costs

The data for this section were not tabulated because of variations in the definitions of some cost elements across sites and among sharing partners. The major costs at each PET site were: equipment amortization; maintenance contracts for the scanner; maintenance contracts for the cyclotron; scanner-related supplies; cyclotron supplies including target materials; and personnel, particularly highly skilled radiochemists, clinical and research specialists, analysts and programmers. Other significant costs included installation and maintenance of pneumatic tube systems used to transport radioactive isotopes between facilities, and start-up funding to cover the overhead costs for the initial years of operations.

In an effort to offset these costs, some sites generated revenue by selling cyclotron products to private PET facilities, while others extended their catchment area to include a broader patient base. At one site the decision was made to maintain low operating costs by purchasing cyclotron products from a private source, rather than producing its own. However, this limited its research capabilities.

One site recommended that, to offset the high and often unexpected maintenance costs of the scanner and cyclotron, an escrow account be established from equal contributions made by the sharing partners. A "roving" maintenance team supported by VHA to service all VHA PET centers was suggested as another potential solution. The disadvantage of this solution is that since technical expertise in PET is limited, there is a considerable likelihood that these technicians would be subsequently recruited by the private sector.

E. Barriers and incentives to PET use

Table 13 lists the barriers and incentives to PET use that were discussed in the interviews, and that may contribute to the range of frequencies seen in Tables 8-12. Statements that appear to conflict reflect the diverse opinions and interests of the interview subjects. Table 14 lists the recommendations mentioned during the interviews for improving the management of PET centers and increasing utilization of PET. In addition, a number of VHA PET centers provided examples of processes with which they had addressed some of these issues; these processes are listed as "best practices" in Table 15. Information regarding issues related to the FDA and trends in utilization may also be found in Table 12.

1. *General issues*- The site visit interviews indicated that there are significant organizational, professional, scientific, and reimbursement issues yet to be resolved before PET becomes more widely diffused. Ambiguities in the interpretation of FDA regulations regarding the use of FDG and other radiotracers for clinical purposes contributed to variations in the authority (federal versus state) under which PET sites chose to govern their operations, and subsequently, in the types of clinical and research PET studies conducted (See Tables 12 and 13). Proposed changes in FDA regulations related to manufacturing practices of radiopharmaceuticals will likely result in modification of operations at most sites. Generic PET issues such as limited FDA approved clinical PET applications and lack of demonstrated clinical utility were felt to perpetuate the perception of the general medical community and regulators that PET is primarily a research tool. These issues were also believed to contribute to inconsistent reimbursement policies.

   Sites that obtained reimbursement for clinical studies generally developed *a priori* consensus-building efforts among payers and providers within their communities in exchange for data collection. Sites less successful in obtaining reimbursement often encountered external organizational and political obstructions

which prevented PET scans from being performed. Clinicians described the pre-approval process, typically conducted on a case-by-case basis by many private payers, as untimely and impractical for many clinical needs. At one site local politics impeded reimbursement; in an effort to counter strong union pressure for comprehensive coverage and lower costs to their members, the state commercial payers applied rigorous coverage exclusion criteria to technologies they classified as "experimental."

VHA contributed significantly to overall PET activity by committing substantial resources toward the initial start-up of twelve PET centers systemwide. Although support for one site was discontinued, the remaining eleven sites continued to receive VHA support for subsequent sharing agreements (at the time of the site visit). Centralized strategic planning involving the distribution, construction and maintenance of these centers was seen as necessary to the overall investment into costly high technologies such as PET. Nevertheless, these processes were described as frustrating, inefficient, and protracted.

PET center operations were thought to be adversely affected by the lack of vision and commitment in Headquarters. For example, one VAMC received funding to purchase PET technology, but not the provisions with which to house it. Likewise, new technologies and their associated services often required support for operations beyond the acquisition year to cover staffing needs and revenue shortfalls in the early start-up years before the centers became fully operational. Funding for replacement parts and maintenance were usually not included in the initial acquisition arrangement. Many administrators expressed concerns of having to support new programs and services with existing funding levels.

Variations in VHA's financial commitment to the PET centers appeared to be related to the degree to which this support was continued by local medical center administrators. The degree of local support was reflected in the content of the sharing agreements, in the commitment to house the PET center and assume its high overhead costs, and in the administrators' tolerance of their centers' financial losses.

Although the PET centers' main mission or focus ranged from a primarily research to a primarily clinical orientation, most sites acknowledged that a mix of clinical and research activity was desirable. Some administrators viewed PET as an expensive but valuable technology for furthering research, expanding clinical services, and enhancing prestige, and were willing to accept some financial losses. An example of this was the willingness of some VAMC administrators to use patient care dollars to finance a PET center with a predominantly research mission. Other PET centers were asked to cut costs. One hospital director threatened to eliminate the PET center, because it had failed to sustain itself financially. (Since the site visit, the university affiliate assumed total financial support of the PET center. The VAMC continues to lease space to them for PET operations.)

2. *Practical considerations*- Interview subjects cited several practical considerations that contributed to volume shortfalls (See Table 13). The technical characteristics of the PET camera affected scanning time, which may have taken from 1.5 hours to several hours. Newer models scanned faster and produced higher quality images. Another frequently noted problem was the availability of radioactive tracers. Their production and use were often timed to coincide with other scheduled studies in an effort to minimize costs, but in doing so, scheduling and access to the scanner may have been affected. Many clinicians expressed the need for more staff education on the clinical applications of PET, although they also acknowledged that its clinical utility needed further study.

Inadequate staffing (particularly radiochemists) was cited as impeding the conduct of certain studies. In VA hospitals, PET centers' hours of operation were frequently curtailed by inflexible tours of duty, restrictions in overtime salary, and restrictions and/or cutbacks in the number of Full Time Equivalent Employees. The ability to conduct PET studies with complex radioactive tracers, whose development is very time- and resource-intensive, is contingent upon the availability and qualifications of its radiochemist. Four PET centers cited the need for a qualified radiochemist as a major influence on the variety and volume of patient studies. The supply of radiochemists in the general PET community is limited; competition for these specialists is intense.

3. *Ratio of VA to non-VA patients*- Several issues contributed to differences in the ratio of VA to non-VA patients studied across sites. The location of the PET center and issues related to patient transport were noted. Difficulties obtaining reimbursement for patient transport to the PET center were cited by the affiliates as an important barrier to access if the center was at the VAMC, whereas transport for VA patients was fully covered by most VAMCs. Location played an important role in determining which patients could be scanned, as patients too medically unstable to be transported were unable to be scanned. Problems specific to VA and to VA patients included poor patient compliance in keeping scheduled appointments and the perception by private sector patients that the quality of care delivered by VHA was substandard, or that the availability of services provided by VA hospitals was restricted to VA patients only. Many PET center directors expressed frustration at not having the authority or resources to properly market their services to the private sector.

Although reimbursement for VA patients' clinical studies was more consistent, the widening disparity of VA to non-VA patients studied in Fiscal Year 1994 (See Tables 8 and 9) indicate that other factors may influence veterans' access to PET. At many sites, VA investigators expressed concern for the lack of available research funding, especially within VHA. The inability to attract VA patients for PET scans may reflect either a lower burden of illness among veterans with respect to the general population, or the disparity between the underlying characteristics of veteran patients, who are frequently more debilitated, and a protocol's inclusion criteria. Moreover, a clinical PET study may not be requested by a referring physician if the test is not felt to contribute information that would increase diagnostic certainty and affect subsequent choice of treatment.

4. *Competition*- Competition at many levels affected the degree to which PET was used. The site visit team observed competition among clinical specialties for access to PET, between PET and other technologies, and among PET centers in the same city. At three sites the use of administrative and regulatory mechanisms to impede some investigators' access to PET was mentioned. At one site, where the PET center was located at the affiliate, an ineffective sharing agreement permitted little recourse on the part of the VAMC with which to gain and maintain equal access; fostered the perception among clinicians that VA administrators valued preserving the relationship between the sharing partners over the interests of the VAMC and its veterans; and allowed for an imbalance in representation of both specialties and sharing partners on the PET Oversight Committee. The site visit team identified one site that developed a process to overcome these barriers based on a model at the National Institutes of Health to facilitate the review and approval of their PET protocols, thereby assuring access to PET for all (See Table 15).

Competing interests from other functional imaging technologies including Single Photon Emission Computed Tomography (SPECT) and functional Magnetic Resonance Imaging (MRI) tended to dilute both administrative and academic support for PET. At several sites, clinicians were more likely to favor SPECT over PET

because of wider acceptance among clinicians and third party payers and greater accessibility to clinicians. Competition with other active PET centers within the community may have affected both the referral base from which private patients were recruited and the ability to attract both PET specialists and scarce research funding.

5. *Referral base*- Strong academic and clinical interests in functional imaging were important incentives for supporting technologies such as PET. The depth and breadth of the clinical and research referral base at each site influenced the types of applications studied, the kinds of patients included in these studies, and the proportion of clinical and research studies conducted. Gaps in selected areas of patient volume were often reflections of low or nonexistent interest of some specialties in PET. The site visit team discovered that neither the depth nor the breadth of the referral base extended far. Intensive recruitment efforts of specialists interested in PET took months in many cases. At one site, the loss of one epilepsy specialist effectively eliminated any activity in that area until recruitment efforts were completed.

Data from Fiscal Year 1995 (See Table 12) suggest a growing interest among referrers, particularly in clinical oncology. This may be due, in part, to the results of educational and marketing efforts made by PET center staff in recent years and to the growing body of PET literature reflecting interest in clinical oncology applications.

6. *Sharing agreements*- The sharing agreement process was cited as reflecting the trust and respect between the partners. All negotiators mentioned the need to balance the relationship between the sharing partners and to protect their individual interests. The negotiating team typically included representatives from Fiscal Service and the Director's Office. The degree to which the Director's Office participated in these negotiations varied across sites; the most active participation produced some of the most successful arrangements (See Table 15). To comply with VA policy (regarding recent changes in policy memo #2) PET directors with dual appointments were excluded from the negotiations. Consequently, the negotiations could not benefit from the insight of the individual who was most familiar with the needs of the service.

Three centers had no sharing agreements with their academic affiliates. In one case the relationship between sharing partners was strained, and in another, the PET center was located at and totally supported by the VAMC. The third center was also located at and supported by the VAMC, but had sharing agreements with local providers and individual researchers, rather than with its academic affiliate.

In these sharing agreements, PET center cost sharing varied from an even distribution between partners to covering partial costs. Those VAMCs sharing the cost burden with academic affiliates typically used estimated volume projections to compute the unit cost needed to meet overhead costs. In all cases, these volume projections were overestimated relative to actual experience. For those VAMCs with payback schedules based on these projections, payback had not been achieved, and the discrepancy was reconciled in other ways. Some sites renegotiated sharing agreements based on more realistic volume projections. One site developed a workload unit to better reflect true utilization of resources (See Table 15).

Some VA administrators expressed concern that the planning and subsequent construction costs of their affiliate's PET centers were extravagant, and that the VAMC was given minimal or no opportunity to participate in the planning. In recognition of this problem and to ensure that the VAMC would not be charged for excessive overhead costs, some sites successfully negotiated a lower patient charge based on an estimated cost or charge equal to the national average (as determined in a survey by the Institute for Clinical PET of PET centers in the U.S.).

Reconciliation of costs for VAMCs that had PET centers located at the academic affiliate were typically handled on a fee-for-service basis via a monthly billing system; the VAMC was charged for PET scans at a reduced rate compared to that of the private sector. Similarly, VAMCs charged for scans conducted on private patients by billing the academic affiliate, which then collected from private payers. The MDRC Technology Assessment Program found that the sharing arrangement most favorable for VAMCs with PET centers located at the academic affiliate was one that allowed for the full payment up front by the affiliate for its portion of the scanner. If contributing toward overhead costs, the VAMC was subsequently billed on a fee-for-service basis at a charge equal to or less than the national average. Another arrangement favorable to VAMCs was one in which a fixed number of "free" scans for VA patients was determined up front, in exchange for partial use of the scanner by other sharing partners. These arrangements insure that each VAMC recovers its portion of the investment up front, without risk of financial loss, should the volume projections be unfulfilled.

7. *Research activity at VHA PET centers*- Table 16 lists the wide range of research protocols available throughout VHA PET centers. Most research activity was in neurology and psychiatry, and to a lesser degree, in cardiology. There is a rapidly growing interest in oncology. Researchers in neurology and psychiatry view PET as critical for the progression of basic research in these areas. Those sites with existing funded research projects were more likely to sustain their research activity by attracting additional research funding and recruiting high level specialists. Most sites have a core infrastructure of nuclear medicine staff with specialized academic interests in functional imaging. One PET center is run by a neurologist with extensive funding in basic science neurology research and who has received substantial administrative support. Variations in research activity across sites reflect the degree to which the academic interests in functional imaging extended into other academic specialties.

PET research studies are generally more complex and quantitative than PET clinical studies. To sustain research activity, the following support was found to be important: state-of-the-art information systems, personnel to operate these systems, software, data analysts, a cyclotron within close proximity to produce the radioisotopes (including those with short half-lives) needed for most research studies, and, as discussed previously, a qualified radiochemist. At all sites, the reputation and expertise of the PET director and core PET center staff contributed positively to the willingness of medical staff and researchers to use PET as a clinical and research tool.

Several sites were found to be conducting similar research, yet many researchers were unaware of past or ongoing activity at other centers. Many researchers (particularly those in psychiatry) noted that they would like to coordinate research activity among sites, to make the most efficient use of available research funding. However, conflicts with interstate use of an Investigative New Drug protocol and the desire of some researchers to work independently affected their ability to cooperate with others.

Table 13: Results of Site Visit Interviews Reflecting Major Barriers and Incentives to the Use of PET Within Each Site

Note: Some comments may appear more than once within each site.

SITE		FACTORS AFFECTING THE USE OF PET			
		TYPE OF APPLICATIONS	**VA/NON-VA PATIENTS**	**CLINICAL/RESEARCH STUDIES**	**OVERALL**
A	Barriers to Use	• *reimbursement limited by restrictive criteria established by state authorities* • *limited approved use of FDG by FDA* • *greater degree of familiarity with and access to SPECT* • *low interest in clinical oncology among SPs*	• *difficulties obtaining reimbursement for ambulance transport* • *location:* - *not favorable for study of medically unstable non-VA patients* - *VA's reputation by private sector for poor quality care* - *perceived by some as only available to VA patients* • *inadequate coordination of services at VA between ER staff and testing labs, plus long wait to obtain most imaging tests make some research protocols not feasible for VA patients* • *conflicts between oncology clinic director and VA administration contribute to low clinical interest in PET* • *low interest in clinical oncology at affiliate*	• *investigators have access to many functional imaging modalities, diluting interest in solely PET* • *PET still viewed by many as a research tool only*	• *pressure by VA administration to become more cost-efficient; need to reduce FTEE of an existing skeletal staff* • *center's ability to develop and become self-sufficient felt to be impeded by lack of vision and commitment within CO* • *PET must compete with other imaging modalities for the support and interest of VAMC administration* • *more parking needed for outpatients* • *difficulties marketing PET services to community*
	Incentives to Use	• *significant level of funded research, particularly in psychiatry and neurology* • *PET viewed by the psychiatric community as critical for the progression of their research*	• *VA patients' scanning costs covered by VAMC* • *location of scanner more favorable to VA patients*	• *access of investigators to many functional imaging modalities, including PET*	• *strong academic interest in functional imaging* • *well integrated clinical staff among SPs*

SP= Sharing Partner

SITE		FACTORS AFFECTING THE USE OF PET			
		TYPE OF APPLICATIONS	VA/NON-VA PATIENTS	CLINICAL/RESEARCH STUDIES	OVERALL
B	Barriers to Use	• *lengthy start up time of ^{15}O-water production needed for neurology research affected credibility of PET center* • *SPECT more readily available to neurologists and psychiatrists* • *PET's clinical utility not demonstrated*	• *location; PET not accessible to unstable VA patients* • *lack of demonstrated clinical utility and restricted FDA approved clinical uses limits reimbursement for non-VA patients* • *non-VA patients covered by managed care require pre-approval, which may take several weeks; not always clinically practical* • *low clinical interest in cardiac PET studies at VA because of limited section budget and clinical utility* • *low interest in brain neuroimaging at affiliate*	• *no research funding obtained*	• *competition with another local active PET center* • *PET's clinical utility not clear:* - *limited approved use of FDG by FDA* - *limited clinical PET expertise among general staff* • *lengthy scan time related to PET's technical characteristics limits patient volume*
	Incentives to Use	• *growing interest in oncology PET applications* • *well-balanced interest of PET director in all PET applications* • *interest in brain neuroimaging in VA at GRECC*	• *VAMC reimburses clinical PET scans* • *interest in brain imaging in VA at GRECC*	• *well-balanced interest of PET director in all PET applications*	• *good working relationship among SPs* • *PET's role in tertiary care academic "centers of excellence" viewed favorably by VAMC administration*
C	Barriers to Use	• *no VA specialists in psychiatry and epilepsy surgery who use PET diagnostically* • *PET's low resolution in evaluating brain tumors* • *competition with MR, CT, SPECT for most clinical needs in psychiatry and neurology* • *inconsistent reimbursement from private sector*	• *no VA specialists in psychiatry and epilepsy surgery who use PET diagnostically* • *difficulties transporting VA patients affected by local topography* • *inadequate parking at VAMC* • *grant funding needed for VA researchers*	• *clinical utility not demonstrated* • *inconsistent reimbursement from private sector*	• *more physician education felt to be needed in PET technology* • *high costs; low reimbursement* • *PET's role in managed care not clear because clinical utility not demonstrated*
	Incentives to Use	• *increasing cardiology interest at VA*	• *increasing cardiology interest at VA* • *VA scans paid for on a fee-for-service basis*	• *research focus of PET center* • *important recruitment tool for attracting high level researchers*	• *well-respected PET center staff* • *PET viewed as important for institutional prestige*

SP=Sharing Partner

SITE		FACTORS AFFECTING THE USE OF PET			
		TYPE OF APPLICATIONS	VA/NON-VA PATIENTS	CLINICAL/RESEARCH STUDIES	OVERALL
D	Barriers to Use	• *perceived preferential scheduling of neurology studies* • *cardiology researchers perceive access to PET obstructed by the PET Operating Committee* • *competition with CT and MR in oncology work up* • *greater access to SPECT for cardiology studies*	• *location of scanner disadvantageous for VA patients* • *little reimbursement for clinical studies performed on non-VA patients*	• *research output affected by limited capabilities of radiochemist* • *little reimbursement for clinical studies for non-VA patients*	• *tension among SPs created by protracted sharing agreement process*
	Incentives to Use	• *expertise of PET director in neurologic applications*	• *reimbursement by VAMC for clinical PET scans on VA patients*	• *strong academic interest in functional imaging*	• *collaboration among SP investigators, especially in neurology and psychiatry* • *reputation of both SPs for delivering high quality patient care*
E	Barriers to Use	• *interest in neurologic PET applications not fostered by affiliate's Department Chair* • *oncologists focused in research areas other than PET*	• *inconsistent reimbursement for non-VA patients*	• *clinical utility not demonstrated* • *no specialist in clinical PET*	• *clinical utility in most areas not demonstrated* • *staff education needed on PET's clinical role* • *difficulties transporting VA patients transport to center*
	Incentives to Use	• *reimbursement for cardiac viability, epilepsy and brain tumors covered in non-VA patients* • *strong academic interest in functional imaging in psychiatry* • *growing interest in clinical oncology applications*	• *favorable reimbursement for VA patients*	• *equal emphasis on clinical and research use by PET director* • *grant-supported research interest in functional imaging*	• *VA considered an important player in the medical complex* • *PET viewed as a powerful recruitment tool* • *VAMC administration supportive of PET* • *clinical research data available to both SPs via development of shared computer archiving system*

SP= Sharing Partner

SITE		FACTORS AFFECTING THE USE OF PET			
		TYPE OF APPLICATIONS	VA/NON-VA PATIENTS	CLINICAL/RESEARCH STUDIES	OVERALL
F	Barriers to Use	• *easier access to and reimbursement for SPECT* • *pre-approval from private insurers required by IRB; impractical for many clinical applications*	• *lack of interest in PET among VA researchers:* - *low funding* - *little administrative support* • *clinical PET studies for VA patients not reimbursed by VAMC*	• *clinical PET studies for VA patients not reimbursed by VAMC* • *center deficient in radiochemistry expertise needed for research studies* • *distance of cyclotron from PET center; unable to scan using short-lived tracers* • *insufficient staff support for research project*	• *little reimbursement; clinical utility not demonstrated* • *VAMC administration unwilling to support PET with patient care dollars* • *strained relationship between SPs at administrative level* • *no nuclear medicine service at VAMC*
	Incentives to Use	• *well-integrated medical staff* • *reimbursement for myocardial viability studies* • *strong academic interest in neurology and cardiology imaging*	• *reputation of VAMC attracts large catchment area; able to recruit patients easily for cardiology and neurology studies*	• *reputation of VAMC as a quality institution* • *funded research interests in cardiology and neurology* • *PET's superior resolution over other modalities useful in some psychiatric research*	• *SPs connected via hallways:* - *facilitates ease of patient transport* - *fosters collegial relationship among clinical staff* • *highly regarded PET director* • *PET useful for recruiting medical staff*
G	Barriers to Use	• *weaker academic ties in cardiology and oncology* • *scanner equipped for brain studies only* • *IRB approval unsuccessful for most cardiology clinical research studies*	• *location of scanner not favorable to non-VA patients*	• *all PET studies require IRB approval; no clinical studies conducted which do not comply with FDA regulations* • *coordination of some research initiatives inhibited by physical distance between SPs*	• *total patient volume limited by finite hours of operation and tours of duty* • *mandatory IRB and RDRC approval of all protocols are perceived as obstruction mechanisms by some*
	Incentives to Use	• *PET director highly regarded for neurology PET expertise* • *strong academic ties in neurology and psychiatry*	• *location of scanner favorable to VA patients* • *new facility and reputation facilitates recruitment of non-VA patients*	• *center supported by funding for neurology PET research*	• *only PET scanner in the state* • *new facility;fosters positive reputation* • *PET center supported by VAMC administration*

SP=Sharing Partner

SITE		FACTORS AFFECTING THE USE OF PET			
		TYPE OF APPLICATIONS	VA/NON-VA PATIENTS	CLNICAL/RESEARCH STUDIES	OVERALL
H	Barriers to Use	• *clinical utility not demonstrated* • *limited FDA approved clinical use of FDG* • *little or no reimbursement for clinical studies*	• *financial hardship on center due to limitations imposed by sharing agreement* • *little funding for VA-sponsored research*	• *limited FDA approved clinical PET applications except for pre-surgical evaluation of epilepsy*	• *location of scanner; all patients require transportation to center* • *staffing limitations; a second radiochemist is needed* - *state mandates presence of radiochemist during cyclotron operations* - *neither SP is able to absorb costs of additional staffing* • *high operating costs*
	Incentives to Use	• *PET core staff expertise in neurologic and psychiatric PET applications* • *cardiology PET specialist recently recruited to staff* • *increasing interest in oncology applications*	• *mostly non-VA research funding obtained for PET studies* • *slow, but growing interest among VA researchers*	• *lengthy but well-coordinated protocol approval process* • *center supported largely by research grants*	• *strong reputation of both SPs within community* • *many successful sharing agreements negotiated between SPs* • *close integration of SPs at many levels* • *highly skilled personnel recruited as core staff* • *very cooperative and congenial atmosphere*
I	Barriers to Use	• *low cardiac research or clinical interest in PET* • *^{15}O-water not available for some neurology studies*	• *center not easily accessible to patients; located in back of hospital*	• *center designed more for clinical, rather than research purposes:* - *full-time radiochemist needed to develop complex tracers* - *PET support staff not always perceived as cooperative* • *location of radiochemistry lab; next to machine shop* • *availability of isotope affects expediency of inpatient testing*	• *daily patient volume restricted by limited operating hours* • *low morale among PET support staff*
	Incentives to Use	• *liberal private sector reimbursement for clinical oncology studies* • *strong academic interest in neurology and psychiatry PET applications*	• *VA patient scanning reimbursed by VAMC* • *location of scanner more favorable for VA patients*	• *reimbursement available for most clinical studies* • *large production capacity of cyclotron* • *VA PET center more accessible to investigators than university*	• *reputation of VAMC* • *PET director respected and liked* • *PET center generates revenue for VAMC; several sharing agreements negotiated with private sector*

SP=Sharing Partner

SITE		FACTORS AFFECTING THE USE OF PET			
		TYPE OF APPLICATIONS	VA/NON-VA PATIENTS	CLINICAL/RESEARCH STUDIES	OVERALL
J	Barriers to Use	• *perceived limited role in cardiac surgery work up* • *inconsistent reimbursement*	• *delays in approval by third party insurers for scanning non-VA patients*	• *no cyclotron or support staff with which to conduct research protocols*	• *conservative medical community ; PET's clinical utility not demonstrated* • *high costs; low reimbursement*
	Incentives to Use	• *centers of excellence in epilepsy treatment and cardiothoracic surgery* • *growing interest in oncology*	• *scanner located at VAMC favorable for VA patients* • *VAMC supportive of PET center*	• *PET director's main focus is clinical PET applications*	• *VAMC respected in medical community* • *PET director highly regarded* • *VAMC supportive of PET center*
K	Barriers to Use	• *lack of reimbursement for more recently developed clinical oncology applications*	• *location of scanner not favorable to non-VA patients because of the following perceptions:* - *PET unavailable to non-VA patients* - *PET viewed as only a research tool* - *quality of care at VA is poor*		• *potential competition from second PET center in area* • *conservative medical community; clinical utility not demonstrated* • *centralized decision making in CO undermines VAMC's ability to adapt to local market changes* • *viability of VA system in question; creates morale problems*
	Incentives to Use	• *rapidly expanding interest in oncology* • *diverse use of PET encouraged by PET director* • *consensus building approach facilitates likelihood of reimbursement*		• *funded research focused in neuroscience* • *approval for reimbursement of clinical studies reached by consensus*	• *VA administration supports PET's role in the tertiary care setting* • *expertise of PET director highly regarded* • *approval for reimbursement of clinical studies reached by consensus*

SP=Sharing Partner

Table 14: Recommendations Volunteered During VHA PET Site Visit Interviews

Note: These recommendations were not part of the formal interview questionnaire, but were offered by some interview subjects during the interview process. Direct quotes are noted; other recommendations are paraphrased based on information obtained from interview summaries.

Recommendations (frequency)
I. Recommendations for/Comments on Improving VA Systemwide
Examples: • *VA must compete more aggressively in the managed care environment if it is to survive.(8)* • *VA should sponsor more MR and/or CT technology centers and conduct advanced studies to become state-of-the-art in these technologies, rather than invest in PET. (4)* • *High technology should be located at regional facilities.(3)* • *VA needs to focus on support facilities (eg. parking), rather than on PET. (1)* • *"Someone in a responsible position needs to review and better prioritize the allocation of funds for and within the VA system." (1)*
II. Recommendations for Improving VHA PET Activity
Examples: • *Each PET program should be reviewed critically in terms of its viability, capacity, and available expertise.(3)* • *"VA should stop supporting university PET centers who don't reciprocate."(2)* • *"There should be a working cooperative group to decide what needs to be done, and the equipment also must be standardized."(1)* • *PET should be judiciously placed throughout the system.(1)* • *A strong multi-disciplinary team is needed to run a PET Center. (2)* • *VA should build PET teams similar to a GRECC (Geriatric Research Education & Clinical Center) at a few locations of high expertise with a steady flow of funds to support these teams to carry out a wide range of studies. (1)* • *"VA should have mandated and funded the PET centers. They (VA) weren't organized as a group to do anything. You've got to set it up to make it work." (1)* • *"You need a paid staff, not just graduate students, making the (cyclotron) materials..." (1)* • *The VA system should create a PET "roving maintenance" team to service all of the PET centers. (3)* • *VA should create a central warehouse for scanner parts and consider a group purchase for upgrade capabilities, using its economy of scale advantage. (1)* • *PET directors need to promote PET's capabilities more. (2)* • *"VA should invest in PET, especially in neurology and psychiatry." (1)* • *When purchasing new equipment (i.e. PET camera), you should obtain the largest field of view possible." (1)*

Recommendations (frequency)
III. Recommendations for Improving PET Sharing Agreements
Examples: • *VA should pursue shared procurement of equipment, start-up funding, and the building as part of the overall initial plan. (1)* • *Strategic planning, which includes "marrying" capital procurement and plant construction, is essential. (3)* • *New sharing agreements should make provisions for equipment upgrades. (2)* • *Sharing agreement negotiations should include, but go no higher than, the office of the regional director to insure that regional needs are considered and duplication within the region is avoided. (1)* • *PET directors with dual appointments should be allowed to participate in sharing agreement negotiations. (1)*
IV. Recommendations for PET Research
Examples: • *VA multi-center studies of the efficacy and cost effectiveness of PET should be done. (15)*   • *The following areas of interest were cited: comparing Thallium reinjection to PET in myocardial viability determination, neurotransmitters, and oncology applications such as ENT, breast, gliomas, solitary pulmonary nodules, and colorectal cancers.* • *VA should support existing centers, but not expand, and use its resources to evaluate the clinical utility of PET and improve its technical capabilities. (7)* • *"The government and third parties must get together to do the research needed to establish the effectiveness of various technologies and fund ways of paying for them." (1)* • *"If VA is going to invest in high technology, they should be more oriented to academic research." (1)* • *VA needs one research consultation center. (1)* • *"VA shouldn't buy more PET scanners for research, but maybe for clinical studies." (1)* • *A comparison between magnetoencephalography (MEG) and PET is needed, because currently MEG has better temporal resolution. (1)* • *"My tax dollars should not pay for clinical PET neurology/psychiatry applications, only research." (2)* • *A PET center should have available hardware for brain research. (1)* • *VA should explore the use of PET in neurodegenerative diseases and evaluating brain tumors. (1)* • *A prospective study comparing SPECT, Thallium and PET with technetium in brain tumors should be done. (1)* • *PET should be compared with Thallium in the detection of vasomotor ischemia. (1)*

Recommendations (frequency)
IV. Recommendations for PET Research (continued)
Examples: • *The future of psychiatric research should involve regional development of ligands so to avoid duplication. (1)* • *VA should invest in PET cardiovascular clinical applications and research. (1)* • *Rapid sequence MRI might be compared with PET in a randomized controlled trial to assess effectiveness in the determination of myocardial viability. (1)* • *Future research should look at using PET to detect the site of the unknown primary tumor. (1)* • *A comparison of PET to Gallium scanning in the detection of residual disease in the treatment of Hodgkin's or non-Hodgkin's disease is needed. (1)* • *VA should invest in cancer studies, in one or two well-funded areas. (1)* • *A clinical trial comparing PET with surgical staging is needed. (1)*
V. Other Recommendations/Comments
• *People need to be educated on the limitations of the (PET) technology. (1)* • *"PET is a technology looking for an application." (3)*

Table 15: Best Practices Identified at VHA PET Sites

Issues Addressed	Approach/Process Description	Site/ Contact Person/ Phone Number
Facilitation of the sharing agreement process	*This site has successfully negotiated several sharing agreements, because the details of the sharing agreements are negotiated primarily by the Director's Office, not by Supply Service. However, approval of these sharing agreements does require concurrence by Supply Service. Underlying the success of these negotiations is the trust and respect which have been developed between the partners over time. Negotiating through the Director's Office offers the following advantages:* *1) the Director's Office carries more weight than Supply Service in the negotiation process;* *2) the Director's Office emphasizes involvement in the whole process, including costs, services exchanged, and personnel involved;* *3) the Director's Office can negotiate details with greater flexibility than Supply Service.*	*San Antonio, TX/* *Louise Parker/* *(210) 617-5220*
Facilitation of the protocol approval process	*The Research Imaging Center (RIC) developed a process, based on an NIH model, whereby PET protocols are typically reviewed and approved within 3-4 weeks from the time of submission. To facilitate this process, the following preliminary steps were developed:* *1) The RIC works closely with other committees such as the Radiation Drug Research Committee, Radiation Safety Committee, and the Investigational Review Board to develop mutually acceptable terminology and the forms necessary to facilitate the approval process;* *2) Potential investigators are encouraged to attend weekly PET "lab" meetings to discuss informally their ideas and obtain feedback from PET experts;* *3) Potential investigators are advised to identify a sponsor, who is a member of the core RIC staff, to act as a mentor. As a mentor, this staff member must have the appropriate expertise in the chosen area of study and be familiar with the protocol approval process to assist with protocol development, which may take several months. Additionally, the mentor agrees to vouch for the integrity of the protocol.* *The investigator proceeds to the Protocol Review Committee, comprised of experts in all related RIC disciplines, for review and approval of his or her PET protocol. All sharing partners are represented, although the focus of representation is interdisciplinary, not institutional. A Scientific Advisory Board has been created whose roles are to monitor the Protocol Review Committee for fairness and to advise them in the direction of studies of particular interest to their respective institutions. Each institution is represented equally by members who report to their facility's director.*	*San Antonio, TX/* *Tuhin Chaudhuri, MD/* *(210) 617-5117* *or* *Peter Fox, MD/* *(210) 567-8150*
Standardization of a method used to measure resources directly utilized in a given PET protocol	*Each approved PET protocol, whether for clinical or investigational purposes, is assigned a relative value unit (rvu) which is used to measure directly the resources utilized in that protocol. A rvu consists of the ratio of personnel services utilized (expressed in hours) to commodities and supplies (at actual cost) utilized and is then compared to that of a definitional unit.* *The specific cost for a given protocol is determined by an assessment of overall programmatic costs divided by the expected program value (in rvu's) and then multiplied by the specific protocol rvu. The assignment of a rvu to a given protocol is subject to the review and concurrence of representatives of both sharing partners and is part of the negotiated sharing agreement process.*	*Ann Arbor, MI/* *Milton Gross, MD/* *(700) 374-7886*
Reimbursement by local payers	*Using group consensus, this site created the Review Council for Clinical PET comprised of the clinical PET community from participating medical facilities, the University, local third party payers, and the Health System Agency from NY State (local regulatory bodies) whose goals are:* *1) to develop consensus on acceptable clinical PET protocols to be reimbursed, and* *2) to authorize physicians who have been trained in PET to read clinical PET scans.*	*Buffalo, NY/* *Jayakumari Gona, MD* *or Alan Lockwood, MD/* *(716) 862-3635*
Reimbursement by local payers Expansion of referral base Determination of the clinical usefulness of PET	*To permit eligibility for third party reimbursement, the state required the PET center to develop demonstration protocols to accomplish the following:* *1) to collect data to determine both the clinical usefulness of PET imaging and the cost impact by comparing the costs of treatment plans of referring physicians before and after PET scanning, and* *2) to allow eligible citizens of the state of Connecticut access to PET imaging.*	*West Haven, CT/* *Robert Soufer, MD/* *(203) 937-3427*

Table 16: Research Activity at VHA PET Sites as of October 1994

Note: Information from Ann Arbor and Pittsburgh was obtained through site visit interviews. All other site information was obtained from the pre-site visit surveys.

Abbreviations are listed at the end of the table.

Description	Site*	Funded (X=yes)	Activity			Study Subject		Comments
			Past	Current	Future	Human	Animal	
NEUROLOGY								
Cognitive disorders								
Psychiatric symptoms on cortical metabolism in Alzheimer's disease	WLA	X		X		X		
PET in people at risk for familial Alzheimer's disease	WLA	X		X		X		
Attention deficit and central executive discontrol in Alzheimer's disease	WLA				X	X		
Prodromal Alzheimer's disease	IND	?		X		X		
Familial Alzheimer's Disease	IND	?		X		X		
Prediction of Alzheimer's disease in a 2 year follow up study	AA	?		X		X		
Exploring the diagnosis and treatment of Alzheimer's disease	PITT	X		X		X		
Measurement of regional cerebral blood flow in patients with known or suspected AIDS dementia complex	MINN	X		X		X		
Measurement of rCMRglc in subjects with known or suspected AIDS dementia complex using F-18-FDG and PET	MINN	X		X		X`		
Differential diagnosis of early dementia	AA	?		X		X		
Neural correlates of visuospatial working memory	MINN							info not provided by investigator
PET and reaction time studies of language processing using O-15 water	MINN							info not provided by investigator
Functional neuroanatomy of human cognition using O-15 water	MINN							info not provided by investigator
PET studies of language function	BUF	X		X		X		
PET studies of hearing loss and tinnitus	BUF	X		X		X		
Neurophysiology of pain	AA	?		X		X		
Motor disorders								
The transplantation of fetal substantia nigra into the caudate nucleus and putamenal nucleus of patients with Parkinsons disease	WH			X		X		

Description	Site*	Funded (X=yes)	Activity			Study Subject		Comments
			Past	Current	Future	Human	Animal	
PET studies of Parkinson's disease	BUF				X	X		approved, not funded
Dopaminergic PET and motor dysfunction in Parkinsonism	MAD	X		X		X		
Measurement of rCMRglc in subjects with known or suspected hereditary or sporadic/acquired ataxia using F-18-FDG and PET	MINN			X		X		
Measurement of rCMRglc in subjects with extrapyramidal movement disorders using F-18-FDG and PET	MINN			X		X		
Measurement of regional cerebral blood flow in patients with ataxia	MINN			X		X		
Functional brain mapping in adults with infantile hemiplegia: A PET study of cerebral plasticity	SA	X		X		X		
Investigation of the neural bases of chronic stuttering	SA			X		X		
NIH program project: stuttering, a movement disorder	BUF	X			X	X		
Studies of non-catecholic l-Dopa analogs	MAD	X		X		X		
PET probes of dopamine neurons in young and aged macaques	MAD	X		X		X		
Epilepsy								
Studies of brain blood flow and metabolic function in epilepsy	WH			X		X		
Collaborative interictal PET imaging of epileptic patients	WH			X		X		
Regional cerebral blood flow and glucose metabolism in patients with complex partial seizures	SA			X		X		
The role of PET in predicting outcome following anterior temporal lobectomy for medically refractory partial complex seizures	PA			X		X		
Pre-frontal dysfunction in frontal lobe epilepsy	WLA	X		X		X		
Functional mapping of the brain to monitor blood flow in epilepsy patients who follow a research paradigm involving naming objects	AA	?		X		X		
Other								
Use of PET imaging for the early detection of malignant degeneration of low grade gliomas	WH			X		X		
Measurement of rCMRglc in subjects with chronic cocainism using F-18 fluorodeoxyglucose and PET	MINN			X		X		
FDG PET imaging of cocaine infusion	WLA	X		X		X		
Measurement of rCMRglc in normal volunteer subjects using F-18-FDG and PET	MINN			X		X		

Description	Site*	Funded (X=yes)	Activity			Study Subject		Comments
			Past	Current	Future	Human	Animal	
Measurement of regional cerebral blood flow in normal volunteer subjects	MINN			X		X		
Activation studies of the normal human frontal lobe	WLA	X		X		X		
Auditory activation	IND	?		X		X		
rCBF activation	IND	?		X		X		
rCBF activation	IND	?		X		X		
$rCMR_{glu}$ control studies	IND	?		X		X		
Human Functional Brain Mapping with PET: Inter-subject variability	SA			X		X		
Human Functional Brain Mapping: Brain representation of body schema	SA			X		X		
Use of high brain/blood partition coefficient inert diffusible blood flow tracers in the detection of local blood flow changes	SA			X		X		
Functional and structural imaging in closed-head trauma	SA	X		X		X		
PET studies of minimal traumatic brain injury	BUF	X		X		X		
O-15 peripheral vascular studies in patients with spinal cord injury	WLA				X	X		
PET studies of hepatic encephalopathy	BUF	X		X		X		
PET and neuropsychological studies of cerebral function in patients with chronic severe ischemic coronary artery disease	BUF				X	X		approved, not funded
Mental function in aging	WLA				X	X		
O-15 cerebral activation studies in patients with Persian Gulf Syndrome	WLA				X	X		
Discordant twins	IND	?		X		X		
GSS Indiana kindred	IND	?		X		X		?? description
Action of morphine in the brain	AA	?		X		X		
PSYCHIATRY								
Mood disorders								
Fluoxetine effects on mood, cognition and metabolism	SA	X		X		X		
Functional neuroanatomy of mood, brain glucose metabolism in idiopathic depression and depression associated with basal ganglia disorders	SA	X		X		X		
Effect of prozac treatment on mood, cognition and brain glucose metabolism in patients with primary unipolar depression	SA	X		X		X		
Functional neuroanatomy of emotion: A PET Brain Mapping study	SA			X		X		

Description	Site*	Funded (X=yes)	Activity			Study Subject		Comments
			Past	Current	Future	Human	Animal	
Affect, depression, and brain asymmetry	MAD	X		X		X		
Affective style: Social and psychobiological substrates	MAD	X		X		X		
Exploring the diagnosis and treatment of depression	PITT	X		X		X		
Evaluating the role of the serotonin system in antidepressant therapy	PITT	X		X		X		
Anxiety/Stress disorders								
PET measurement of benzodiazepine receptors in stress	WH	X			X	X		
PET and SPECT measurement of the benzodiazepine receptor in anxiety	WH	X		X		?		
PET measurement of the benzodiadepine receptorwith C-11 iomazenil in patients with anxiety disorders and healthy subjects	WH	X		X		X		
Neurobehavioral correlates of PTSD symptoms in combat veterans	MINN	?				X		info not provided by investigator
PET measurement of cerebral metabolic correlates of yohimbine administration in PTSD and healthy controls	WH			X		X		
CNS activation during episodes of mental stress induced myocardial ischemia	WH	X		X		X		
PET evaluation of treatment for simple phobia	PA		X			X		
Other								
Exploring the diagnosis and treatment of schizophrenia	PITT	X		X		X		
Chemical exposure	IND	?		X		X		? description
Human biological clock	IND	?		X		X		?description
CARDIOLOGY								
Metabolic effects of chronic myocardial hibernation and reperfusion using FDG and O-15 water	MINN	X	X				X	
Myocardial glucose utilization following cardiac surgery	MINN		X				X	
Imaging myocardial perfusion	SA			X		X		
Imaging myocardial viability	PA,SA, IND	X,X,?		X		X		
Imaging myocardial ischemia	PA,SA,IND	X,X,?		X		X		
Screening of healthy volunteers for possible inclusion in a myocardial PET imaging study	SA			X		X		
Role of PET with FDG in conjunction with maximal exercise stress in the assessment of chronic stable coronary artery disease	SA	X		X		X		

Description	Site*	Funded (X=yes)	Activity			Study Subject		Comments
			Past	Current	Future	Human	Animal	
Studies of cost effectiveness of cardiac diagnostic studies	BUF	X			X	X		
Comparative accuracy of rest-redistribution Thallium SPECT vs. FDG PET in predicting reversibility of left ventricular dysfunction following coronary artery bypass surgery	PA		X			X		
A comparison of Rb-82 PET and TI-201 SPECT in the evaluation of CAD	PA		X			X		
The acute effects of cigarette smoking on myocardial perfusion as evaluated by PET	PA		X			X		
Noninvasive PET imaging of cardiac transplant patients	PA		?			X		
Heart dosimetry of 18-F-FDG	PA				X	X		
Evaluation of ischemic heart disease in women: clinical center	PA	X			X	X		under review
Pathogenesis of symptomatic vs. silent myocardial eschemia	WLA			X		X		
Myocardial perfusion by Cu-60 copper PTSM with PET	MAD	X		X		X		
Indicators of metabolism within a perfusion-viability gradient	MAD	X		X		X		
Measuring women's response to cardiac stress with circulating estrogen to explain false positive thallium stress results and replace cardiac caths with PET	PITT	X		X		X		
Exploring severe heart failure and the use and mechanism of beta-blockers	PITT	X		X		X		
ONCOLOGY								
The role of PET-FDG in detection of occult cervical lymph node metastases	MINN			?		X		
Applications of PET in colorectal carcinoma patients	BUF			X		X		
Use of FDG PET scanning to stage esophageal cancer	BUF			X		X		
Lymph node metastases	IND	?		X		X		
Staging patients with lymphoma using whole body imaging	AA	X		X		X		
Lymph node involvement in patients with malignant melanoma	AA	X		X		X		
Staging of the mediastinum for non small cell lung cancer	AA	X		X		X		
Evaluating solitary pulmonary nodules	AA	?		X		X		
Monitoring chemotherapy in the treatment of breast cancer	AA	X		X		X		
Defining the variable needed to monitor physiologic changes in tumors prior to tumor shrinkage after chemotherapy	PITT	X		X		X		

Description	Site*	Funded (X=yes)	Activity			Study Subject		Comments
			Past	Current	Future	Human	Animal	
OTHER								
Studies of dialysis disequilibrium	BUF	X		X		X		
PET studies of inhaled 11-C-triamcinolone	BUF	X		X		X		
Clinical evaluation of the Argus PET system	MAD	X	X			X		
Pancreatic blood flow	IND	?		X		X		
Skeletal muscle	IND	?		X		X		

Abbreviations:
AA=Ann Arbor
BUF=Buffalo
IND=Indianapolis
MAD=Madison
MINN=Minneapolis
PA=Palo Alto
PITT=Pittsburgh
SA=San Antonio
WH=West Haven
WLA=West LA

IV. SUMMARY

It has been only until recently that all VHA PET centers have become fully operational, thus allowing for an assessment of their activity. The information from the pre-site visit surveys indicated that there are significant variations in the characteristics of the PET centers and in the types, volumes and purposes of the PET studies across all sites. Information from site visit interviews indicated that there are important organizational, professional, scientific, and reimbursement issues yet to be overcome before PET becomes more widely diffused. Recommendations volunteered by some of the interview subjects including processes by which to overcome some of these barriers (See Table 14) were presented, and may be helpful to administrators, researchers and clinicians.

Although there is a growing interest in clinical PET studies, PET is still viewed by regulators and the general medical community as a research tool. PET has made a significant contribution to overall research activity within VHA and continues to be the primary research tool for certain areas of research, particularly in the neurosciences.

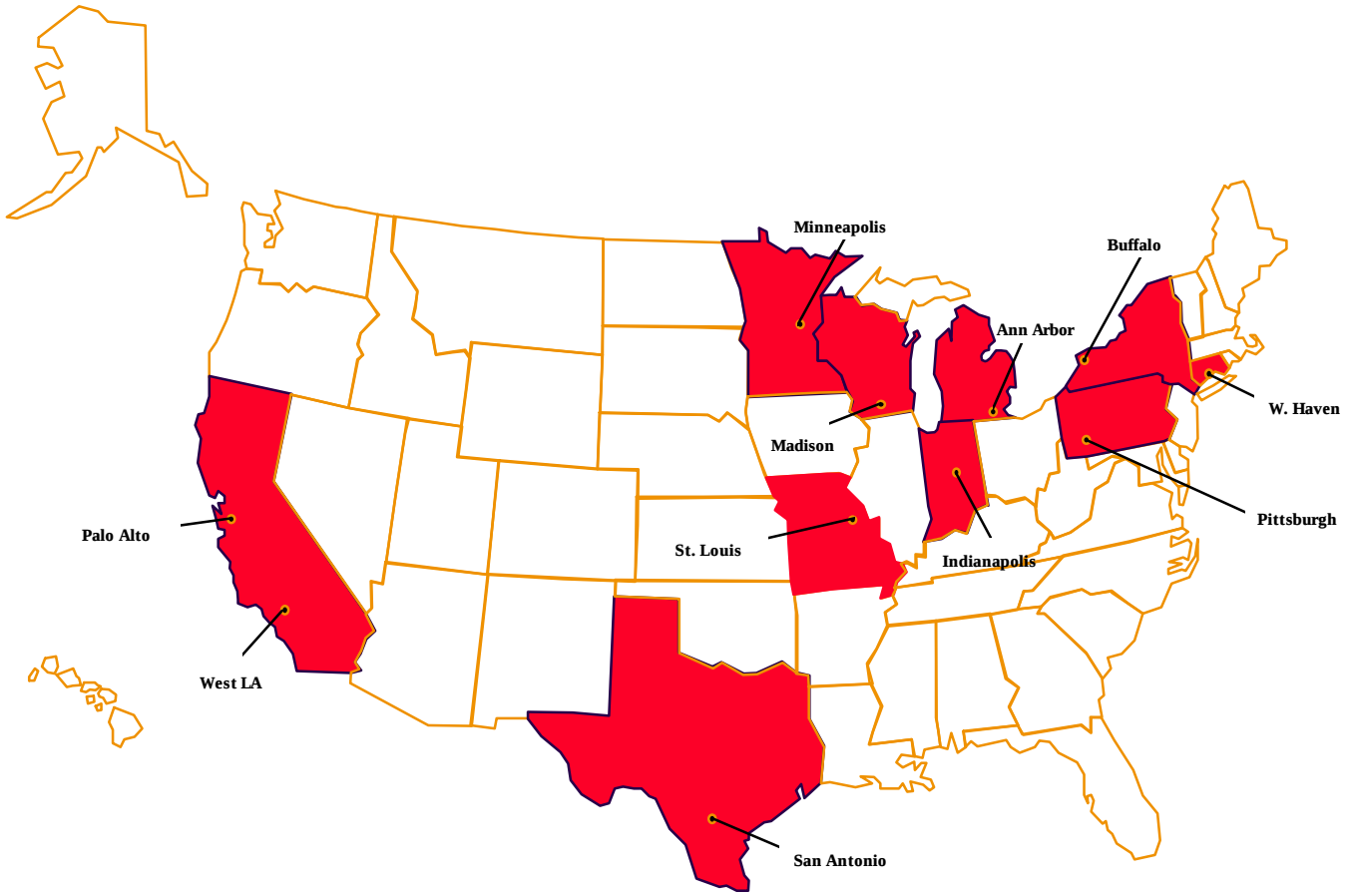

Fig. 1 Locations of VHA PET Centers

Name of PET Center: _____

PRE-SITE VISIT SURVEY

I. GENERAL INFORMATION

1) On average, how many hours/day is the PET Center in operation? _____hours/day
2) On average, how many days/week is the PET Center in operation? _____days/week
3) On average, how many days/week is the PET Center available to VA patients? ____days/week
4) On average, how many weeks/year is the PET Center open? _____weeks/year
5) Is the PET Center operational on federal holidays? ____yes ____ no
6) On average, how many days/year is downtime experienced for:
   _____ scheduled maintenance _____ emergency maintenance
7) Is the PET Center affiliated with an academic institution? ___ yes ___ no If yes, what is the affiliate's name?_____
8) Who is responsible for scheduling patients?___VA ___Affiliate ___Center (freestanding)

II. PET SYSTEMS

1) What year did PET become operational at your site?_____
2) What is the current name and model of your PET camera? _____
3) Has there been an upgrade in equipment since you first became operational? ___ yes ___ no
4) Is the scanner located at VA? ___ yes ___ no If located off-site, how many miles away from your facility is the scanner? _____ miles
5) Does your facility own a cyclotron? ___ yes ___ no (If no, go to #6) If yes:
   a) Where is it located?_____
   b) What is the current name, model, and age of the cyclotron? _____
   c) Which products are generated from this cyclotron?

   d) Do you supply cyclotron-generated radiopharmaceuticals to other PET facilities? __yes __ no
      If yes, how much revenue was generated from your cyclotron products in
      FY "92? $_____ FY '93? $_____ FY '94? $_____
   e) What mode (s) of transportation (i.e. plane, truck, pneumatic tube, etc.) is/are used to deliver radiopharmaceuticals(s) to your PET facility? _____
      to other PET facilities? _____

GO TO #7

6) Does your PET Center use cyclotron products? ___ yes ___ no (Go to #7) If yes:
   a) Where are these cyclotron products manufactured? _____
   b) What mode(s) of transportation (i.e. plane, truck, pneumatic tube, etc.) is/are used to deliver radiopharmaceuticals(s) to your PET facility? _____
7) Does your PET center use generator-produced radiopharmaceuticals for PET? ___ yes ___ no (If no, go to #8) If yes:
   a) Where are these generator products manufactured? _____
   b) What mode(s) of transportation (i.e. plane, truck, pneumatic tube, etc.) is/are used to deliver radiopharmaceuticals(s) to your PET facility? _____
8) Do you supply generator-produced radiopharmaceuticals to other PET facilities? ___ yes ___ no (If no, go to #9) If yes:
   a) Do you supply cyclotron-generated radiopharmaceuticals to other PET facilities? __yes __no
      If yes, how much revenue was generated from your cyclotron products in
      FY "92? $_____ FY '93? $_____ FY '94? $_____
   b) What model(s) of transportation (i.e. plane, truck, pneumatic tube, etc.) is/are used to deliver radiopharmaceuticals(s) to your PET facility?_____
      to other PET facilities? _____
9) Does your facility have a Rubidium generator? ___ yes ___ no If yes:
   a) What is the name, model and age of the generator? _____

III. PERSONNEL

1) To help us determine the salary costs attributed directly to PET, please complete the following tables for information on current staff:

Existing Staff Expertise	*#VA FTEEs*	*VA Salary & Benefits*	*% Grant Funded*	*#Non-VA FTEEs*	*Non-VA Salary & Benefits*	*% Grant Funded*
Physician **See chart below	XXX	XXX	XXX	XXX	XXX	XXX
Radiochemist						
Medical Physicist						
Radiopharmacist						
Nuclear Med Tech						
Chem Tech						
RN						
Administrator						
Director(if non-physician)						
Secretary/ Receptionist						
Other:						

Physician Expertise (Give Specialty)	*VA-based Salary & Fringe ($)*	*% Grant Funded*	*% Total VA Time Devoted to PET Center Clinical or Research Applications*	*% Total VA Time Devoted to PET Center Administration*
1.				
2.				
3.				
4.				

2) Are there other positions that need to be filled for successful operation of your PET facility? ___

If yes, please indicate:

opened positions _____

positions to be created _____

3) Do you provide on-the-job training for your PET Center staff? ___ yes ___ no

4) Do you participate in a formal instructional program designed to train PET personnel? __yes __ no

5) To determine each staff member's function(s) at your PET facility, please check (√) the box(es) that correspond(s) to the appropriate function(s) of each staff member:

Staff Expertise	***Running Cyclotron***	***Eluting Generator***	***Quality Control***	***Radiolabelling Synthesis***	***Administering Dose to Patient***
Physician					
Radiochemist PhD					
Radiochemist Tech					
Medical Physicist					
Radiopharmacist					
Nuclear Med Tech					
Chem Tech					
RN					

IV. RESEARCH

1) Attach a list of past and current research projects performed by your facility involving PET since FY 92. Indicate whether or not they are funded, source of funding, and any resulting publications.

2) Attach a list of any proposed projects in PET application areas that are planned for your facility and/or with your university affiliates.

V. SPACE REQUIREMENTS

1) To determine issues that may affect the use of PET, please indicate how much space is currently allocated for:

Cyclotron _____ sq. ft. Is this adequate? _____ yes _____ no
PET camera _____ sq. ft. Is this adequate? _____ yes _____ no
Electronics/control room _____ sq. ft. Is this adequate? _____ yes _____ no
Radiochemistry Lab _____ sq. ft. Is this adequate? _____ yes _____ no
Shop facilities _____ sq. ft. Is this adequate? _____ yes _____ no
Administration _____ sq. ft. Is this adequate? _____ yes _____ no
Waiting area _____ sq. ft. Is this adequate? _____ yes _____ no
parking spaces for PET Center _____ sq. ft. Is this adequate? ____yes ____ no

VI. ANCILLARY SERVICES

1) To identify the difference(s) between PET sites with respect to potential referral sources, please indicate whether or not these services exist at your VA or University affiliate:

Service	***Yes***	***No***	***Service***	***Yes***	***No***
Alcohol Dependency Treatment Unit			Neuropsychological Testing		
Cardiac Cath Lab			Nursing Home Care Unit		
Cardiac ICU			Patient Health Ed. Program		
Cardiac Surgery Program			PFT Lab		
Electron Microscopy			Sickle Cel l Screening Program		
Hemodialysis and CAPD Trainig			Speech Pathology Lab		
Hypertension Screening and Treatment Program			Surgical ICU		
Medical ICU			Geriatric Research Education & clinical Center (GRECC)		
Mental Hygiene Clinic			Women's Health Center		
PTSD Program			Health Psychology Program		
Epilepsy Program			Cancer Center		
Other:			Other:		

2) To identify the potential referral base of each PET facility, please fill in the following table and be as complete as possible:

Specialty	***Affiliated Residency or Fellowship Program at VA?***		****Potential Referring **VA Physicians in Each Specialty***	***Number of **VA Physicians Who Have Referred***	****Potential Referring Non-VA Physicians in Each Specialty***	***Number of Non-VA Physicians Who Have Referred***
	Yes	***No***				
Cardiology						
Oncology						
Neurology						
Psychiatry						
Pulmonary						
Internal Medicine						
ENT						
Oncology						
Gynecology						
GI						
Other:						
Surgical:						
Cardiac						
Neuro						
Other:						

*Note: "Potential Referring" physician is defined as a Physician who would refer patients from his/her clinical practice, not onw who is strictly a researcher.

**Note: "VA physician" is defined as a physician who is employed by VA for 5/8 time or greater. This information may be available through your Chief of Staff.

VII. BUDGET

1) To identify costs attributed directly to PET, please fill in the following table:

Item	*Total FY '92 Costs*	*Total FY '93 Costs*	*Total FY '94 Costs*
FIXED SUPPLIES:			
Cyclotron			
Generator-Related			
Maintenance Contract for Cyclotron			
Maintenance Contract for Camera			
Insurance			
Other:			
VARIABLE SUPPLIES:			
Film			
Purchased Radiopharmaceuticals**			
Other Pharmaceuticals i.e. Persantine, Adenosine			
Cyclotron Supplies Including Target Materials			
Patient Supplies			
Camera-Related Supplies Including Rod Source			
Other:			

**If a non-cyclotron or non-generator site

VIII. OTHER

1) What is your definition of clinical PET?

Name of PET Center: _____

Interview Questionnaire- PET Chiefs

1. How long have you been at this VA facility?
2. What is your current title? previous title?
3. Were you involved in the planning of this PET facility?
    a. Who else was involved?
    b. Who made the decision as to whether or not PET would be available at this facility?
4. Could you explain your facility's PET Sharing Agreement?
5. Does the availability today of PET for VA patients differ from expectations specified in the Sharing Agreement?____ yes _____no
    a. If yes, in what ways?
    b. Why do you think this is the case?
6. With respect to planning for PET, if a sharing agreement were renegotiated, what would you do differently?
7. What does having access to PET technology mean to this facility? (financial implications, status, etc.)
8. What kinds of financial and administrative support have been provided for this PET facility, i.e.:
    a. Was space provided?
    b. Was a building provided?
    c. Was start-up funding provided?
    d. Who gets third party revenue?
    e. Provisions for marketing?
    f. Others?
9. Have you had difficulties obtaining reimbursement for PET scans? Explain.
10. What barriers can you think of that affect the use of PET?
    a. What has the VAMC done to contribute to, eliminate or reduce these barriers?
11. Does this facility have MR capabilities? CT? SPECT?
    a. What generation is the equipment?
    b. What are its capabilities?
    c. Has it impacted the use of PET? If so, how?
12. Hypothetical: If you were starting from scratch a could afford to buy only one state-of-the-art imaging technology, which one would you buy and why?

13. Where do you see this VAMC going 3-5 years down the road with respect to the managed care environment?
    a. What do you see as PET's role in this?

THE FOLLOWING QUESTIONS ARE BASED ON THE PRE-SITE VISIT QUESTIONNAIRE:

14. Are there problems scheduling VA patients for PET scanning?___yes ___no
    a. What are those problems?
15. What percentage of scans are inpatients? outpatients?
16. Where is the closest PET facility?
    a. How long does it take to get there?_____minutes
17. Are there any other geographic factors that affect access?
    a. If yes, what are they?
18. How many personnel do you have?
19. Did you experience difficulties in recruiting personnel for PET?____yes ___no
    a. If yes, please explain:
20. Do you currently have any vacancies? ____yes ____no
    a. If yes, what positions are vacant?
21. How will staff expertise be recruited to these new positions?
22. (See Section III #3) If on-the-job training is provided, describe what kinds of training is provided**:**
23. (See Section III #3) If a formal instructional program is provided, describe what kinds of training is provided**:**
24. Please list any workshops, presentations, grand rounds, etc. given as an effort to educate and inform the medical staff at your facility of PET:
25. Have the efforts listed above resulted in a change in the number of referrals to your PET facility?____yes ____ no.
    a. If yes, please describe in terms of volume and types of scans requested:
26. How active is the affiliated university medical center in the PET Center in terms of the proportion of time and equipment used?
27. Do you have other collaborative efforts with other institutions, facilities or providers? _____ yes _____ no.
    a. If yes, please describe them:
28. Are there opportunities for sharing resources beyond what your program is doing?
    a. Please describe what they might be:

Name of PET Center: _____

Specialty: _____

Interview Questionnaire- Physicians

1 Are you employed by VA? _____yes _____no
   a. If yes, what percentage of time is devoted to VA?
   b. Do you attend at the University Hospital? _____yes _____no
2. Are you employed by the University? _____yes _____no
   a. If yes, what percentage of time is devoted to the University?
   b. Do you attend at the VAMC? _____yes _____no
3. How long have you worked for: VA?_____yrs University?_____yrs
4. Is your interest primarily clinical, research or both?
   a. How is your time divided between clinical, research, administration and other duties?
5. Do you have a lab? _____yes _____no
6. Do you see patients? _____yes _____no
7. How did you first learn about PET technology?
8. How did you first learn about PET at your facility?
9. Do you refer patients for PET scans? _____yes _____no
10. If you do not refer, why not?
11. If you do refer, for what conditions? For each condition give the following information:
   a. Is this a research protocol and/or is this used for clinical purposes?
   b. What tests are ordered prior to your ordering a PET scan?
   c. In this situation, what does PET give you that the other tests or technologies do not?
   d. If PET is ordered for clinical purposes, for what percentage of patients with this condition is PET ordered?
   e. Can you also give absolute numbers?
12. Have you experienced problems scheduling patients for PET?
   a. If so, what are these problems?
13. Do your colleagues believe in PET?
   a. How many refer vs. how many do not refer?
14. Are there any other issues to discuss?